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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,030	09/21/2001	Hideaki Yagi	Q66254	4266
7590	02/27/2004		EXAMINER	
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC 2100 Pennsylvania Avenue, NW Washington, DC 20037-3213			RAGONESE, ANDREA M	
			ART UNIT	PAPER NUMBER
			3743	10
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/957,030	YAGI ET AL.
	Examiner	Art Unit

Andrea M. Ragonese

3743

CJP

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 January 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) 15 and 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date Z. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response to Amendment

1. The amendment filed on January 7, 2004 has been entered. Examiner acknowledges that **claims 1, 3, 4 and 9-11** have been amended and **claim 17** has been added.

Response to Arguments

2. Applicant's arguments with respect to **claims 1-16** have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

4. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

5. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. **Claims 1-17** are provisionally rejected under the judicially created doctrine of double patenting over claims 1-12 of copending Application No. 09/956,924 or over claims 1, 4-10, 12, 14-22 and 24-32 of copending Application No. 09/956,925. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

7. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: oxygen supply apparatus with a sensor for detecting the state of breathing of the user.

8. Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Objections

9. **Claims 15-16** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically,

dependent **claim 15** recites a controller which does not properly further limit the oxygen supply apparatus as claimed in **claim 1**. In addition, dependent **claim 16** recites a recording medium which does not properly further limit the controller as claimed in **claim 15** or the oxygen supply apparatus as claimed in **claim 1**.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 1, 2 and 6-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. (US 4,681,099) in view of Mitchell et al. (US 5,590,648). Sato et al. discloses an oxygen supply apparatus 1 which supplies oxygen or oxygen-enriched gas to a user 22 having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of the user 22 by means of a breath

synchronization function (column 4, lines 37-44 and column, 6, lines 40-59), as shown in Figure 1, which comprises:

- a sensor **28** for detecting the state of breathing of the user **22** (column 4, lines 54-58 and column 7, lines 41-49);
- means **29** for judging the state of breathing of the user **22** under a predetermined judgment condition when breath-synchronized operation is performed, based on a signal from the sensor **28** (column 4, lines 59-column 5, line 8 and column 8, lines 29-47);
- an oxygen cylinder **23** filled with oxygen, or an oxygen enriching apparatus **1** which enriches oxygen contained in air (column 4, lines 45-50);
- wherein the sensor **28** is disposed at an oxygen outlet **26** to which oxygen or oxygen-enriched gas is supplied and is adapted to detect the state of a gas at that position (column 7, lines 41-49);
- wherein the oxygen supply apparatus **1** is an oxygen enriching apparatus **1**;
- when the breath-synchronized operation is not performed, the oxygen enriching apparatus supplies the oxygen-enriched gas at a flow rate equal to or less than a continuous base flow rate, that is the flow rate at which the oxygen enriching apparatus **1** can supply the oxygen-enriched gas continuously (column 6, line 60-column 7, line 9);
- when the breath-synchronized operation is performed, the oxygen enriching apparatus **1** supplies the oxygen-enriched gas during the inhalation period of a breathing cycle at a flow rate greater than the continuous base flow rate and

stops supply of the oxygen-enriched gas during the exhalation period of the breathing cycle (column 11, line 64-column 12, line 12), as shown in Figures 7A-7C;

- when the breath-synchronized operation is performed, the oxygen enriching apparatus 1 supplies the oxygen-enriched gas during the inhalation period of a breathing cycle at a flow rate greater than a continuous base flow rate, that is the flow rate at which the oxygen enriching apparatus 1 can supply the oxygen-enriched gas continuously, and supply the oxygen-enriched gas during the exhalation period of a breathing cycle at a flow rate less than the continuous base flow rate (column 11, line 64-column 12, line 12); and
- wherein the continuous base flow rate is 4 liters/min or less (column 7, lines 19-30), as depicted in Table 2.

Based on the description above, it is apparent that Sato et al. discloses an apparatus comprising all the limitations recited in **claims 1, 2 and 6-14**, with the exception of means for supplying the oxygen or oxygen-enriched gas to the user over a predetermined period when no breathing is detected and a sensor disposed at a breath detection port provided separately from an oxygen outlet. However, the use of a ventilator for supplying oxygen to a patient when a sensor indicates that breathing has stopped was known at the time the invention was made. Specifically, Mitchell et al. teaches the use of sensor **20a** (column 3, lines 17-33) for indicating that breathing has stopped and then supplying oxygen continuously to the patient during this time period (column 4, lines 39-column 5, line 3) was known at the time the invention was made.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Sato et al. to sense that the patient's breathing has stopped through the use of a sensor located at a breath detection port and then continuously supply oxygen to the patient because, as taught by Mitchell et al., it is well-known in the art to sense a patient's breathing pattern in order supply oxygen continuously to a patient when the patient is not breathing.

13. **Claims 3-5 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sato et al. (US 4,681,099) in view of Mitchell et al. (US 5,590,648). Based on the description in paragraph 12, it is apparent that Sato et al. in view of Mitchell et al. discloses an apparatus comprising all the limitations recited in **claims 3-5 and 17**, but does not expressly disclose the specific duration of the time period during which the state of breathing of the user cannot be detected. At the time of the invention was made, the general rate of respiration and the duration of inspiration of a human being were well known. Therefore, it would have been obvious to one having ordinary skill in the art to set the predetermined period to correspond to the lowest average breathing rate of a human being as Applicant has done and further correspond to that portion of the inhalation cycle that corresponds to inhalation since this is the period during which the user takes in gas. Moreover, Applicant has not asserted that the specific predetermined periods recited provide a particular advantage, solve a stated problem or serve a purpose different from that of any other period derived from the range of average human respiration. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with different time periods that

reasonably correspond to the average breathing rate of a human being because oxygen would be provided to the human being in a manner that is adequate. Therefore, it would have been obvious to modify the apparatus of Sato et al. in view of Mitchell et al. to obtain the invention as specified in **claims 3-5 and 17**.

14. Given the fact that applicant recites the combination of a controller for controlling operation of an oxygen supply apparatus and the oxygen supply apparatus itself [see claim objection in paragraph 9 of this Office action], **claim 15** is rejected under 35 U.S.C. 103(a) as being anticipated by Sato et al. (US 4,681,099) in view of Mitchell et al. (5,590,648). Specifically, it appears that **claim 15** is limited to the controller itself as a subcombination. Given this interpretation, the cited prior art is considered applicable to the claimed invention. Sato et al. discloses a controller **29** for controlling an oxygen supply apparatus **1** which supplies oxygen or oxygen-enriched gas to a user **22** having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of the user **22** by means of a breath synchronization function (column 4, lines 37-44 and column, 6, lines 40-59), as shown in Figure 1. Based on the description in paragraph 12, it is apparent that Sato et al. discloses an apparatus comprising all the limitations recited in **claim 15**, with the exception of means for supplying the oxygen or oxygen-enriched gas to the user over a predetermined period when no breathing is detected and a sensor disposed at a breath detection port provided separately from an oxygen outlet. However, the use of a ventilator for supplying oxygen to a patient when a sensor indicates that breathing has stopped was known at the time the invention was made. Specifically, Mitchell et al. teaches the use of sensor **20a** (column 3, lines 17-33)

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for indicating that breathing has stopped and then supplying oxygen continuously to the patient during this time period (column 4, lines 39-column 5, line 3) was known at the time the invention was made. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Sato et al. to sense that the patient's breathing has stopped through the use of a sensor located at a breath detection port and then continuously supply oxygen to the patient because, as taught by Mitchell et al., it is well-known in the art to sense a patient's breathing pattern in order supply oxygen continuously to a patient when the patient is not breathing.

15. Given the fact that applicant recites the combination of a recording medium having recorded thereon means for executing the function of a controller [see claim objection in paragraph 9 of this Office action], a controller for controlling operation of an oxygen supply apparatus and the oxygen supply apparatus itself, **claim 16** is rejected under 35 U.S.C. 103(a) as being anticipated by Sato et al. (US 4,681,099) in view of Mitchell et al. (US 5,590,648). Specifically, it appears that **claim 16** is limited to the recording medium itself as a subcombination. Given this interpretation, the cited prior art is considered applicable to the claimed invention. Sato et al. discloses a recording medium **53** (column 9, lines 4-16) having recorded thereon means for executing the function of a controller **29**, wherein the controller **29** is utilized for controlling operation of an oxygen supply apparatus **1** which supplies oxygen or oxygen-enriched gas to a user **22** having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of the user **22** by means of a breath synchronization

function (column 4, lines 37-44 and column, 6, lines 40-59), as shown in Figure 1. Based on the description in paragraph 12, it is apparent that Sato et al. discloses an apparatus comprising all the limitations recited in **claim 16**, with the exception of means for supplying the oxygen or oxygen-enriched gas to the user over a predetermined period when no breathing is detected and a sensor disposed at a breath detection port provided separately from an oxygen outlet. However, the use of a ventilator for supplying oxygen to a patient when a sensor indicates that breathing has stopped was known at the time the invention was made. Specifically, Mitchell et al. teaches the use of sensor **20a** (column 3, lines 17-33) for indicating that breathing has stopped and then supplying oxygen continuously to the patient during this time period (column 4, lines 39-column 5, line 3) was known at the time the invention was made. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Sato et al. to sense that the patient's breathing has stopped through the use of a sensor located at a breath detection port and then continuously supply oxygen to the patient because, as taught by Mitchell et al., it is well-known in the art to sense a patient's breathing pattern in order supply oxygen continuously to a patient when the patient is not breathing.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jacobs (US 3,794,026), Ellestad (US 4,256,101), Ellestad et al. (US 4,357,936), Smith et al. (US 4,823,788), Yamada (US 5,316,009), Brady et al. (US 5,385,142), Froehlich et al. (US 5,503,146), Sasso, Jr. (US 5,603,315) and Bliss et al.

(US 6,289,890 B1) all disclose breathing sensors for use with oxygen supply apparatuses.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is (703) 306-4055. The examiner can normally be reached on Monday through Thursday from 8 am until 4 pm ET.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

amr
February 23, 2004

Henry Bennett
Supervisory Patent Examiner
Group 3700